

WHAT IS CLAIMED IS:

1 1. A heart valve prosthesis having a plurality of  
2 leaflets encircling a flow opening and of size to  
3 coapt to form a valve, each leaflet having a free  
4 outflow edge at the outflow end of the leaflet,  
5 wherein the free outflow edge forms a convex (relative  
6 to the leaflet) curve in the plane of the leaflet.

1 2. A method for forming a heart valve prosthesis  
2 comprising the step of forming a plurality of leaflets  
3 joined to encircle a flow passage and of a size to  
4 coapt to form a valve, wherein each leaflet has a free  
5 outflow edge at the outflow end of the leaflet,  
6 wherein the free outflow edge forms a convex (relative  
7 to the leaflet) curve in the plane of the leaflet.

1 3. A method for forming a heart valve prosthesis  
2 comprising the steps of:  
3 assembling the valve, by steps comprising forming  
4 a plurality of leaflets joined to encircle a flow  
5 passage and of a size to coapt to form a valve, and  
6 forming an outer sheet joined to the leaflets around  
7 an inflow end and along commissures formed where  
8 adjacent leaflets join;  
9 after assembly of at least the leaflets and outer  
10 sheet of the valve, shaping the leaflets and/or outer  
11 sheet to a desired shape; and  
12 fixing the leaflets and/or outer sheet of the  
13 valve in the desired shape.

1 4. The method of claim 3 wherein the leaflets and  
2 outer sheet are shaped to a desired shape and fixed in  
3 the desired shape, and wherein the shaping of the  
4 outer sheet is of a portion of the outer sheet on the  
5 outflow side of the join between the outer sheet and  
6 the leaflets around the inflow end.

1     5.   A method for forming a stentless heart valve  
2     prosthesis comprising the steps of:  
3         forming a plurality of leaflets joined to  
4     encircle a flow passage and of a size to coapt to form  
5     a valve; and  
6         forming an outer sheet joined to the leaflets  
7     around an inflow end and along commissures formed  
8     where adjacent leaflets join;  
9     wherein the join between the outer sheet and the  
10    leaflets around the inflow end is at the periphery of  
11    the leaflets, and the outer sheet extends by a  
12    distance between 0.3 and 4mm beyond the join with the  
13    leaflets at the inflow end, on the inflow side of the  
14    join, or the join between the outer sheet and the  
15    leaflets around the inflow end is at the periphery of  
16    the outer sheet, and the leaflets extend by a distance  
17    between 0.3 and 4mm beyond the join with the outer  
18    sheet at the inflow end, on the inflow side of the  
19    join.

1     6.   The method of claim 5, further comprising the  
2     step of after assembly of at least the leaflets and  
3     outer sheet of the valve, shaping the leaflets and/or  
4     outer sheet to a desired shape and fixing the leaflets  
5     and/or outer sheet of the valve in the desired shape.

1     7.   The method of claim 5 wherein each leaflet has a  
2     free outflow edge at the outflow end of the leaflet,  
3     wherein the free outflow edge forms a convex (relative  
4     to the leaflet) curve in the plane of the leaflet.

1     8.   The method of claim 7 wherein the leaflets and/or  
2     outer sheet are shaped to a desired shape by inserting  
3     a shaping device into a pocket formed by a leaflet and  
4     the outer sheet.

1 9. The method of claim 8 wherein the shaping device  
2 is a ball formed of a resilient material, preferably  
3 cotton wool.

1 10. The method of claim 6 wherein the leaflets and  
2 outer sheet are assembled from pericardium which has  
3 not been fixed, and fixing the leaflets and/or outer  
4 sheet of the valve in the desired shape is performed  
5 by treatment with glutaraldehyde.

1 11. The method of claim 6 wherein after assembly and  
2 fixing of the valve the outer sheet is trimmed close  
3 to the join between the outer sheet and the leaflets  
4 on the outflow side of the join.

1 12. A valve obtainable by the method of claim 5.

1 13. A stentless heart valve prosthesis comprising a  
2 plurality of leaflets joined to encircle a flow  
3 passage and of a size to coapt to form a valve, an  
4 outer sheet joined to the leaflets around an inflow  
5 end and along commissures formed where adjacent  
6 leaflets join, wherein the join between the outer  
7 sheet and the leaflets around the inflow end is at the  
8 periphery of the leaflets, and the outer sheet extends  
9 by a distance between 0.3 and 4mm beyond the join with  
10 the leaflets at the inflow end, on the inflow side of  
11 the join, or the join between the outer sheet and the  
12 leaflets around the inflow end is at the periphery of  
13 the outer sheet, and the leaflets extend by a distance  
14 between 0.3 and 4mm beyond the join with the outer  
15 sheet at the inflow end, on the inflow side of the  
16 join.

1 14. The heart valve prosthesis of claim 13 wherein  
2 the outer sheet of the valve has a shape resembling  
3 the shape of natural aortic sinuses.

1 15. The heart valve prosthesis of claim 13 wherein  
2 the outer sheet is trimmed close to the join between  
3 the outer sheet and the leaflets on the outflow side  
4 of the join.

1 16. The heart valve prosthesis of claim 13 wherein  
2 each leaflet has a free outflow edge at the outflow  
3 end of the leaflet, wherein the free outflow edge  
4 forms a convex (relative to the leaflet) curve in the  
5 plane of the leaflet.

1 17. The heart valve prosthesis of claim 13 wherein  
2 the valve has three leaflets.

1 18. The heart valve prosthesis of claim 13 wherein  
2 the valve is stentless.

1 19. The heart valve prosthesis of claim 1 wherein the  
2 valve comprises an outer sheet joined to the leaflets  
3 around an inflow end and along commissures formed  
4 where adjacent leaflets join.

1 20. The heart valve prosthesis or claims 13 wherein  
2 the leaflets and/or outer sheet (where present) are  
3 formed from material other than natural valve  
4 material.

1 21. The heart valve prosthesis or claim 20 wherein  
2 the leaflets are formed from a sheet material.

1 22. The heart valve prosthesis or claim 20 wherein  
2 the leaflets and/or outer sheet are formed from a  
3 biological material.

1 23. The heart valve prosthesis or claim 22 wherein  
2 the leaflets and/or outer sheet are formed from  
3 pericardium.

1 24. The heart valve prosthesis or claim 13 wherein  
2 the leaflets are formed by a single piece of sheet  
3 material.

1 25. Cancelled.

1 26. Cancelled.

1 27. A method of repairing a heart valve comprising  
2 the step of providing a heart valve prosthesis as  
3 defined in claim 13, and suturing the heart valve  
4 prosthesis to the heart or blood vessel tissue of the  
5 patient.

1 28. A method of repairing a heart valve comprising  
2 the steps of:

3 (1) providing a valve prosthesis as defined in  
4 any one of the preceding claims, wherein the valve has  
5 an outer sheet;

6 (2) if not already done, trimming the outer sheet  
7 close to the join between the outer sheet and the  
8 leaflets on the outflow side of the join; and

9 (3) suturing the valve prosthesis to the heart or  
10 blood vessel tissue of the patient with a single  
11 suture row.

1 29. A stentless heart valve prosthesis suitable for  
2 replacement of the aortic root comprising an outer  
3 wall and a plurality of leaflets positioned inside the  
4 outer wall, encircling a flow opening and of size to  
5 coapt to form a valve, wherein the outer wall and  
6 leaflets are formed from material other than natural  
7 valve material.

1 30. A method for forming a stentless heart valve  
2 prosthesis suitable for replacement of the aortic root  
3 comprising the steps of forming an outer wall and a

4 plurality of leaflets positioned inside the outer  
5 wall, encircling a flow opening and of size to coapt  
6 to form a valve, wherein the outer wall and leaflets  
7 are formed from material other than natural valve  
8 material.

1 31. A stentless heart valve prosthesis suitable for  
2 replacement of the aortic root comprising a plurality  
3 of leaflets joined to encircle a flow passage and of a  
4 size to coapt to form a valve, an outer wall joined to  
5 the leaflets around an inflow end and along  
6 commissures formed where adjacent leaflets join,  
7 wherein the outer wall and leaflets are formed from  
8 material other than natural valve material, wherein  
9 the join between the outer wall and the leaflets  
10 around the inflow end is at the periphery of the  
11 leaflets, and the outer wall extends by a distance  
12 between 0.3 and 4mm beyond the join with the leaflets  
13 at the inflow end, on the inflow side of the join, or  
14 the join between the outer sheet and the leaflets  
15 around the inflow end is at the periphery of the outer  
16 sheet, and the leaflets extend by a distance between  
17 0.3 and 4mm beyond the join with the outer wall at the  
18 inflow end, on the inflow side of the join.

1 32. The heart valve prosthesis of claim 31 wherein  
2 the outer wall is formed from a biological material  
3 (other than natural valve material) and a non-  
4 biological, biocompatible material.

1 33. The heart valve prosthesis of claim 32 wherein  
2 the outer wall is formed from pericardium and a woven  
3 fabric, preferably polyester (PET).

1 34. The heart valve prosthesis of claim 31 wherein  
2 the leaflets are formed from a biological material,  
3 for example pericardium.

1 35. The heart valve prosthesis of claim 31 wherein  
2 each leaflet has a free outflow edge at the outflow  
3 end of the leaflet, wherein the free outflow edge  
4 forms a convex (relative to the leaflet) curve in the  
5 plane of the leaflet.

1 36. The method of claim 30 comprising the steps of:  
2 assembling the valve, by steps comprising forming  
3 a plurality of leaflets joined to encircle a flow  
4 passage and of a size to coapt to form a valve, and  
5 forming an outer wall joined to the leaflets around an  
6 inflow end and along commissures formed where adjacent  
7 leaflets join;  
8 after assembly of at least the leaflets and outer  
9 wall of the valve, shaping the leaflets and/or outer  
10 wall to a desired shape; and  
11 fixing the leaflets and/or outer wall of the  
12 valve in the desired shape.

1 37. The method of claim 30 comprising the steps of:  
2 forming a plurality of leaflets joined to  
3 encircle a flow passage and of a size to coapt to form  
4 a valve; and  
5 forming an outer wall joined to the leaflets  
6 around an inflow end and along commissures formed  
7 where adjacent leaflets join;  
8 wherein the join between the outer wall and the  
9 leaflets around the inflow end is at the periphery of  
10 the leaflets, and the outer wall extends by a distance  
11 between 0.3 and 4mm beyond the join with the leaflets  
12 at the inflow end, on the inflow side of the join; or  
13 the join between the outer wall and the leaflets  
14 around the inflow end is at the periphery of the outer  
15 wall, and the leaflet extends by a distance between  
16 0.3 and 4mm beyond the join with the outer wall at the  
17 inflow end, on the inflow side of the join.

1 38. The method of claim 37 further comprising the  
2 steps of after assembly of at least the leaflets and  
3 outer wall of the valve, shaping the leaflets and/or  
4 outer wall to a desired shape and fixing the leaflets  
5 and/or outer wall of the valve in the desired shape.

1 39. The method of claim 38 wherein the leaflets  
2 and/or outer sheet are shaped by inserting a shaping  
3 device into a pocket formed by a leaflet and the outer  
4 wall.

1 40. The method of claim 39 wherein the shaping device  
2 is a ball formed of a resilient material, for example  
3 cotton wool.

1 41. The method of claim 38 wherein the outer wall is  
2 shaped to a desired shape and fixed in the desired  
3 shape.

1 42. The method of claim 38 wherein the leaflets and  
2 outer sheet are assembled from pericardium which has  
3 not been fully fixed, and fixing the leaflets and/or  
4 outer sheet of the valve in the desired shape is  
5 performed by treatment with glutaraldehyde.

1 43. The method of claim 37 wherein the outer wall or  
2 sheet has a height ( $h_o$ ) that is between 1 and 15 cm,  
3 preferably between 4 and 12 cm, still more preferably  
4 between about 8 and 10 cm greater than the maximum  
5 height ( $h$ ) of the leaflets.

1 44. A stentless heart valve prosthesis suitable for  
2 replacement of the aortic root obtained or obtainable  
3 by a method according to claim 37.



1 45. The heart valve prosthesis of claim 44 wherein  
2 the outer sheet of the valve has a shape resembling  
3 the shape of natural aortic sinuses.

1 46. The heart valve prosthesis of claim 44 wherein  
2 the valve has three leaflets.

1 47. The heart valve prosthesis of claim 44 wherein  
2 the leaflets are formed by a single piece of sheet  
3 material.

1 48. Cancelled

1 49. Cancelled.

1 50. A method for repairing a heart valve comprising  
2 the step of providing a valve prosthesis according to  
3 claim 44, and suturing the valve prosthesis to the  
4 heart or blood vessel tissue of the patient.

1 51. The method of claim 50 comprising the step of  
2 trimming the outer wall to the desired length,  
3 depending on the extent of aortic tissue to be  
4 replaced.